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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,715	02/13/2002	Michael Chopp	1059.00073	9739

7590 11/01/2005

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,715	CHOPP ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed 9/16/05. Claims 1-13 are pending in the office action. Applicant's request for reconsideration of the rejection of the claims in the last office action is being considered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Claim Rejections - 35 USC § 112

The rejection of claims 1-13 under USC § 112 second paragraph is moot in view of the amendments of claims 1-13.

Claim Rejections - 35 USC § 102

Claims are drawn to a therapeutic compound of promoting neurogenesis, in a pharmaceutical acceptable carrier, that increases level of CGMP, augmenting nitric oxide, such as L-arginine.

Claims 2 - 5 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Moskowitz US 5385940.

Moslowitz teaches of a nitric oxide donor to be -L-arginine (column 2 line7). Growth, augumenting to a site in need of - does not alter the compound nor the composition. The Moskowitz patent discloses L-arginine (see, e.g., the abstract, column

3) as a nitric oxide releasing compound. Consequently, the reference: anticipates the claimed invention defined in claims 2-5 and 13.

Claims 2 - 4 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Poluha et al., J. of biological Chem. Vol 272(38) pp24002-7.

Poluha teaches the current claims 2 and 4- a nitric oxide donor to be nerve growth factor NGF) (see abstract), of neuron growth, (pp 24006 end of 1st paragraph), augmenting to (a site in need of see fig 1. Poluha also teaches of increase levels of CGMP (see page 24005 last paragraph) using NGF. Poluha teaches that treating PC12 cell with the nerve growth factor leads to production of nitric oxide (abstract and entire paper) and nitric oxide results in an increase in cGMP (ref, P 24005, left column, which makes claim 2 anticipated. The poluha et al. reference also teaches (p 24005, leq column) that another results is neutrite extensionti.e., effecting neurogenesis (current claim 1-3). The compound meeting criteria of claim 13 is NGF.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-8 of copending Application No.10/075,715. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is claimed in the copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method of promoting new neuron growth, administering a therapeutic amount of nitric oxide. The only difference between the instant application and the co-pending application is with respect to increase levels of cGMP in the instant claims, while the co-pending application is to ie., promoting or affecting neurogenesis (new neuron growth), the current application claims are directed to increase levels of cGMP which is an obvious variation. Thus the claims of the instant application are within the scope of the co-pending application.

Claim Rejections - 35 USC § 103

Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al in view of Moskowitz and Poluha et.al J. of biological Chem. Vol 272(38) pp24002-7 for reasons of record.

Cunningham et al disclose methods of promoting promoting neurogenesis (see column 17. lines 4-6), augmenting the production of neurons (see column 17, lines 4-6), and increasing neurological and cognitive functions (see column 17, lines 4-17) by

administering a neurotrophic factor or nerve growth factor (NGF) (i.e. therapeutic compound), see column 1, lines 35-38, column 15, lines 48-49, column 17, lines 4-17. The increased levels of CGMP result in vivo by administering the therapeutic compound to a patient in need thereof. Thus, the increased levels of CGMP are inherent to the teachings of the cited disclosure. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to promote neurogenesis (see column 17, lines 4-6), augmenting the production of neurons (see column 17, lines 4-6), and increasing neurological and cognitive functions (see column 10, lines 4-17) by administering a neurotrophic factor or nerve growth factor (NGF) (i.e. therapeutic compound), see column 1 , lines 35-38, column 15, lines 48-49, column 17, lines 4-17, via administration of the compound because it is taught to promote neurite giowth, and administered to a stroke patient or the like (column 4 line54-62). Therefore, CGMP levels would have been expected to be increased in vivo as a result of the administration of the NGF factor or therapeutic compound. For example, one of skill at the time the claimed invention was made would have been motivated to aaminister a therapeutic compound for promoting neurite growth for increasing cognitive ahd neurological functions, to a post stroke patient, as well as promoting neurogenesis and augmentation of neurons. Neurogenesis is defined as increased or enhance neural growth. Cunningham et al teaches of neuron growth in column 4 lines 57-67. Augumentation is defined as enhanced or suppressed growth.
Cunningham teaches NGF as an enhancing neurite growth at column 16 lines 3-10. Therefore, one of ordinary skill would have expected successful results because the

prior art recognizes that neurite growth can be enhanced and increased. The claims in the alternative are, therefore, considered to be prima facie obvious over the cited prior art.

Further, a pharmaceutical carrier is taught at column I7 line 65. (the neurogenesis promoter is taught at column 1 line 35-38 and column 4 lines 54-60, the treatment of stroke is taught at column 4 lines 54-60), administered to a site in need of taught at column column 17 lines 44-46).

Moskowitz teaches of a therapeutic compound for treating neurological disorders such as stroke using nitric oxide (L-arginine as the nitric oxide donor see, e.g., the abstract, column 3), administered to a site taught at column 3 lines 55-58.

Poluha et al teaches increasing CGMP with nitric oxide compounds and NGF (see discussion on page 24005 column 1 lines24-29). The claims differ from the disclosure of Cunningham et al in that the therapeutic compound administered is L-arginine but a nitric oxide donor. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the compound of Cunningham with the compound of Moskotiwz and Poluha in order to provide for a therapeutic compound and methods for promotion of neurogenesis, augumentation of neurons, cognitive and neurological functions as taught by the cited prior art.

Moskowitz specifically disclosed the compound L- arginine as a nitric oxide donor (column 2 lines 1-10), as Poluha et al clearly teach of a nerve growth factor activated pathway involving nitric oxide in the regulation of neural growth (page 24003 column 1 line 5). Moskowitz clearly teach of the administering of the nitric oxide donor to a stroke

patient or after the episode has occurred (column 3 line39-41). The carrier taught by Moskowitz to be a pharmaceutical although they did not specifically teach pharmaceutical it is obvious of the said teaching column 3 line 44-54). In the absence of the persuasive evidence the claims are rendered prima facie obvious. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Cunningham, Poluha and Moskowits to give neuron growth, augments, increase CGMP levels at the site in need of to, a patient suffering from neurodegenerative disorders such as stroke. One of ordinary skill in the art would have expected successful result for administering L-arginine to give neuron growth, increase levels of CGMP and augument.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/12/05

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